JUL 24 2008 K081351

510(K) Summary
Smith & Nephew Smith & Nephew Journey Unicondylar Femoral Implant

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 East Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6017
CONTACT PERSON:	Nicholas B. Tabrizi
DATE SUMMARY PREPARED:	May 2, 2008
TRADE OR PROPRIETARY DEVICE NAME:	Smith & Nephew Journey Unicondylar Femoral Implant
COMMON OR USUAL NAME:	Unicompartmental Knee Prosthesis
CLASSIFICATION NAME:	Knee joint femorotibial metal/polymer semi constrained cemented prosthesis, 21 CFR 8888.3520
DEVICE CLASS:	Class II
PANEL CODE:	Orthopaedics/87/HSX

A. INTENDED USE:

The Journey Unicondylar Knee System is indicated for restoring either compartment of a knee that has been affected by the following:

1. Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. Correction of functional deformity;
3. Revision procedures where other treatments or devices have failed; and
4. Treatment of fractures that are unmanageable using other techniques.

The Journey Unicondylar Knee System components are single use only and are intended for implantation only with bone cement.

B. DEVICE DESCRIPTION:

The devices, subject of this Premarket Notification, are the Smith & Nephew, Inc. Journey Unicondylar Femoral Implant components. The Journey unicondylar femoral implants are intended for cemented medial and lateral tibiofemoral replacement. The femoral implants will be offered in both Cobalt Chrome and Oxidized Zirconium alloy (OXINIUM) materials in sizes 1 through 7. The Smith & Nephew Journey Unicondylar femoral components feature the same articular surface geometry as existing femoral implants cleared in K073175.

The Journey Unicondylar femoral components are intended to be used in combination with the Competitor Unicondylar All-Poly Tibial Baseplates (K061779), or the Competitor Unicondylar Knee Tibial Baseplates and Polyethylene Inserts (K061011).

C. SUBSTANTIAL EQUIVALENCE INFORMATION:

The Smith & Nephew Journey Unicondylar Femoral Implant is similar to the following commercially available devices regarding design features, overall indications, and materials:

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Journey Unicondylar Femoral Implants	K073175	12/28/2007
Smith & Nephew, Inc.	GENESIS Unicompartmental Knee System	K912735	12/27/1991
Smith & Nephew, Inc.	Unicondylar Femoral Component	K030301	02/25/2003
Zimmer, Inc.	Unicompartmental Knee System	K033363	01/10/2004

D. SUMMARY OF TECHNOLOGICAL COMPARISON:

The intended use, design, and materials of the Journey Unicondylar Femoral Implants are substantially equivalent to the previously cleared Journey Unicondylar Femoral Implants (K073175). Design Control Activities have been completed and the results indicated that the subject device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
Orthopaedic Division
% Mr. Nicholas B. Tabrizi
1450 East Brooks Road
Memphis, TN 38116

JUL 24 2008

Re: K081351
Trade/Device Name: Smith & Nephew Journey Unicondylar Femoral Implant
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prothesis
Regulatory Class: Class II
Product Code: HSX
Dated: June 24, 2008
Received: July 1, 2008

Dear Mr. Tabrizi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

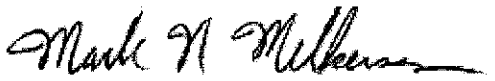
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Smith & Nephew Journey Unicondylar Femoral Implant

Indications for Use:

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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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